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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,414	05/30/2001	Anton-Lewis Usala	35626/234825	7087

826 7590 11/30/2004

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EXAMINER

GUPTA, ANISH

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/870,414	USALA, ANTON-LEWIS	
	Examiner	Art Unit	
	Anish Gupta	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 01 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1-2-02</u> <u>01-16-04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed, 9-10-04, has been acknowledged. Claims 1 and 32 were amended and claim 52 was added. Claims 1-52 are pending in this application.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 9-10-04 has been considered by the examiner.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

4. The rejection of claims 1-6, 16-17, 28, 31, are rejected under 35 U.S.C. 102(b) as being anticipated by Schacht et al. (WO98/55161) is hereby withdrawn.

Claim Rejections - 35 USC § 103

5. The rejection of claims 1-10, 14, 16-28, 31-35, and 37-44, 46 under 35 U.S.C. 103(a) as being unpatentable over Usala (US 5824331) in view of Jude et al. and Miller is hereby withdrawn.
6. Claims 1-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Usala (WO00/02999) in view of Miller et al. in further view of Davis or Pickart et al. remain rejected for the reason set forth in the previous office action under Usala in view of Miller and the reasons set forth below.

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7. Claims 1-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Usala (US 6231881) in view of Miller et al. in further view of Davis or Pickart et al. remain rejected for the reason set forth in the previous office action under Usala in view of Miller and the reasons set forth below.

The claims are drawn to a method of treating an ulcer by the administration of a hydrogel matrix comprising gelatin and a long chain carbohydrate.

For both rejections Applicants argue that the secondary reference, Miller, defines “vascular repair” as reconstructive vascular surgery, and only suggest that such treatment would be successful for ischemic ulcers. For neuropathic ulcers, the reference actually teaches away from microvascular-related treatment since the reference suggest that intrinsic micro-vascular disease is not major etiology factor in such ulcers. Nothing in Miller suggests that a composition that induces microvasculature formation would be successful in the treatment of diabetes related ulcer. The rejection, relying upon “vascular repair,” has taken the phrase to broadly.

Applicants arguments filed, 9-10-04, have been fully considered but have not been found persuasive.

Miller et al. states that an ulcer goes through granulation and reepithelialization (see page 761). Further, the reference suggest that numerous agents can be administered to the to the ulcer site to provide an optimal environment for healing. These include antibiotics and growth factors that result in the stimulation of granulation of tissue (see page 762, paragraph bridging column 1 an d2). It is well known in the art that granulation of tissue consists of new blood vessel formation, fibroblast activity, and re-epithelialization (see col., lines 29-35 of Davis US 5487899 and Col. 1, lines 28-35 of Pickart et al. US 5059588). Thus, unlike Applicants contentions, the Miller teaches vascular repair as a component of treating diabetic foot ulcers. Given that the primary reference

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teaches hydrogels, that are liquid and can be injected at the wound site, are effective in vascularization, i.e. new blood vessel formation, it would be obvious to treat the diabetic foot ulcers using the compositions of Usala. One would expect vascularization to lead to granulation of the tissue and ultimate treatment of the ulcer. Applicants have made a distinction between neuropathic and ischemic ulcers. However, it should be noted that the claims do not make such a distinction. In fact, claim 1 is generic to any type of ulcer treatment.

For this reason the rejection is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-29-31-42, 46-48, and 50-51 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-57 of U.S. Patent No. 6,261,587 in view of Miller and in further view of Davis or Pickart et al.

The claims are drawn to a method of treating an ulcer by the administration of a hydrogel matrix comprising gelatin and a long chain carbohydrate.

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Applicants make similar point for Miller as outlined above. Applicants also stress that Miller defines vascular repair as reconstructive vascular surgery and does not suggest that a composition capable of forming microvasculature would be suitable for the treatment of any type of diabetes-related ulcer. "There is nothing in Miller to suggest that the severe vascular compromise that is a characteristic of ischemic ulcers would be overcome by localized microvasculature at the site of the ulcer.

Applicant's arguments filed, 9-10-04, have been fully considered but have not been found persuasive.

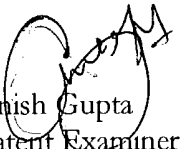
Miller et al. states that an ulcer goes through granulation and reepithelialization (see page 761). Further, the reference suggests that numerous agents can be administered to the ulcer site to provide an optimal environment for healing. These include antibiotics and growth factors that result in the stimulation of granulation of tissue (see page 762, paragraph bridging column 1 and d2). It is well known in the art that granulation of tissue consists of new blood vessel formation, fibroblast activity, and re-epithelialization (see col., lines 29-35 of Davis US 5487899 and Col. 1, lines 28-35 of Pickart et al. US 5059588). Thus, unlike Applicants' contentions, the Miller teaches vascular repair as a component of treating diabetic foot ulcers. Given that the primary reference teaches hydrogels, that are liquid and can be injected at the wound site, are effective in vascularization, i.e. new blood vessel formation, it would be obvious to treat the diabetic foot ulcers using the compositions of Usala. One would expect vascularization to lead to granulation of the tissue and ultimate treatment of the ulcer. Applicants have made a distinction between neuropathic and ischemic ulcers. However, it should be noted that the claims do not make such a distinction. In fact, claim 1 is generic to any type of ulcer treatment.

Rejection is maintained.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can normally be reached on (571) 272-0974. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

 11/24/04
Anish Gupta
Patent Examiner